563

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (201) 331-2901

August 28, 1997

WARNING LETTER

RELENCE

REVIEWED BY VPR 8-29-97
C.O. DATE

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED
Mr. David Jemini
President
Jem Tech, Inc.
135 Gaither Drive
Suite C
Mt. Laurel, NJ 08054

FILE: 97-NWJ-48

Dear Mr. Jemini:

During an inspection of your firm on July 7, and July 14, 1997, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211) in conjunction with your firm's manufacturing/transfilling of liquid oxygen, USP. These deviations cause your drug product(s) to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act as follows:

1. Your firm cannot assure the identity of liquid oxygen, USP received in a drug product container or vehicle mounted vessel, and used in the manufacture and distribution of medicinal gases for home respiratory care patients. For example:

   A. Liquid oxygen, USP manufactured from Nov. 1996 to July 1997, was transfilled from bulk supplier [redacted], lot numbers 076L620 through 184M707, into cryogenic home units for distribution to respiratory care patients, without your firm performing a specific identity test on each lot nor witnessing the testing performed by your supplier.

   B. Your failed to calibrate the [redacted] oxygen analyzer against a known standard gas.

   C. Your firm lacks completed batch production records.

2. Your firm lacks written procedures and/or process controls, for the receipt, quarantine, processing, release and distribution of liquid oxygen, USP.

3. Your firm lacks maintenance and cleaning procedures and documentation to demonstrate that your equipment, used to deliver oxygen to respiratory patients, was maintained and purged in accordance with written procedures.

4. Your firm lacks a training program for those employees engaged in manufacturing/transfilling of liquid oxygen, USP.

NWJ-DO received your written response on August 18, 1997, regarding the list of Inspectional Observations (FDA-483) issued to your firm on July 14, 1997. We now offer the following comments regarding the aforementioned response. Your projected time frame of 60 days to create SOPs is excessive. Furthermore, your response indicated that copies were attached, (refer to #1 and #5 of your response), however, the response received did not include any documentation to demonstrate compliance with cGMPs. Please note that the weight/scale system, (item #4 of your letter), is no longer a compliance requirement. Your current method of volume displacement is adequate if included in your written SOP's. Also, it was noted that your firm uses the [redacted] oxygen analyzer to conduct identity and strength testing. We want to caution you to check the manufacturer's operating/instruction manual to determine the accuracy of the [redacted]. Any oxygen analyzer used for strength testing must have an accuracy of +/-0.1%. We will confirm the actual corrective actions during the next inspection of your facility.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the good manufacturing practice regulations. Until these violations are corrected, Federal agencies will be informed that FDA recommends against the award of contracts for affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

Should your firm have additional comments concerning the FDA-483 or the above points, it should notify this office in writing, within 15 working days of receipt of this letter.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attention: Vincent P. Radice, Compliance Officer.

Very truly yours,

Douglas I. Ellsworth

DOUGLAS I. ELLSWORTH
District Director

VPR:slw

HFA-224
HFC-210 (Div. Compliance Policy)
HFC-120 (Medical Products Quality Staff)
HFI-35 (Purged)
HFD-300 (CDER)
HFD-320 (Sylvia)
HFR-MA350 (DIB/Gp. V McCullough/Glapion)
PSAU
EF (Jem Tech, Mt. Laurel, NJ)

CFN: 2248673
Trak 3 No. 97-896